

PATIENT REGISTRATION AND ENROLLMENT SYSTEM (PRES) USER GUIDE

NOVEMBER 2020

VERSION 2.1

PRES User Guide

DOCUMENT REVISIONS

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INTRODUCTION

Patient Registration and Enrollment System (PRES) is an application that allows the user to register and enroll patients into trial protocols.

The user interface (UI) is a Web Application compatible with Google Chrome, Microsoft Edge, Mozilla Firefox, and Apple Safari. It has been developed by the Office of Information Technology, CCR, NCI, NIH, that also supports and updates the system.

GETTING TO PRES

To access PRESS, open your preferred Web Browser and enter <https://pres.ccr.cancer.gov> in the URL bar. PRES is only accessible while connected to the NIH network.

LOGIN

Users are prompted to login by entering a Username and Password (NIH username and password).

PRES Login

Login

Username
jaddap2

Password
.....

Login

WARNING NOTICE:

This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.


This system is provided for Government-authorized use only.


Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or


FIGURE 1 - LOGIN SCREEN


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If you are not able login or you receive an error message, please use the “Need assistance? Click here!” button located at the lower left part of the home page. This will display the [Issues and Feedback](#) menu. Help button also present in upper right side before Login/Logout button on every page. Help page lists User Manual link, API Documentation, Pharmacy App Instructions and frequently asked questions (FAQs)


 Help

 [User's Manual](#)

 [Pharmacy App Instructions](#)


 [API Documentation](#)


Frequently Asked Questions:


What browsers are supported?


PRES supports following browsers


- Google Chrome
- Mozilla Firefox
- Microsoft Edge
- Safari on macOS

I am new to PRES, whom should I contact for access?

I can not login to PRES, what should I do?

I see error "Unable to login due to Internal Server error. Please try after few minutes", what should I do?

PRES website does not load, All I see is blank white screen?

How do I contact support?

Still Need Help? Click below on **Need Assistance** button

USEFUL LINKS

At the bottom of the login page and every page in the application, the user will find links to useful functions, policies and organizations.

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HOME PAGE

After entering a valid Username and Password, the system will redirect you to the home page. The tiles on the home page will enable the user to access different sections based on the user's privileges. The tiles that appear in the figure below belong to a System Admin. Other users will not be able to see all sections.

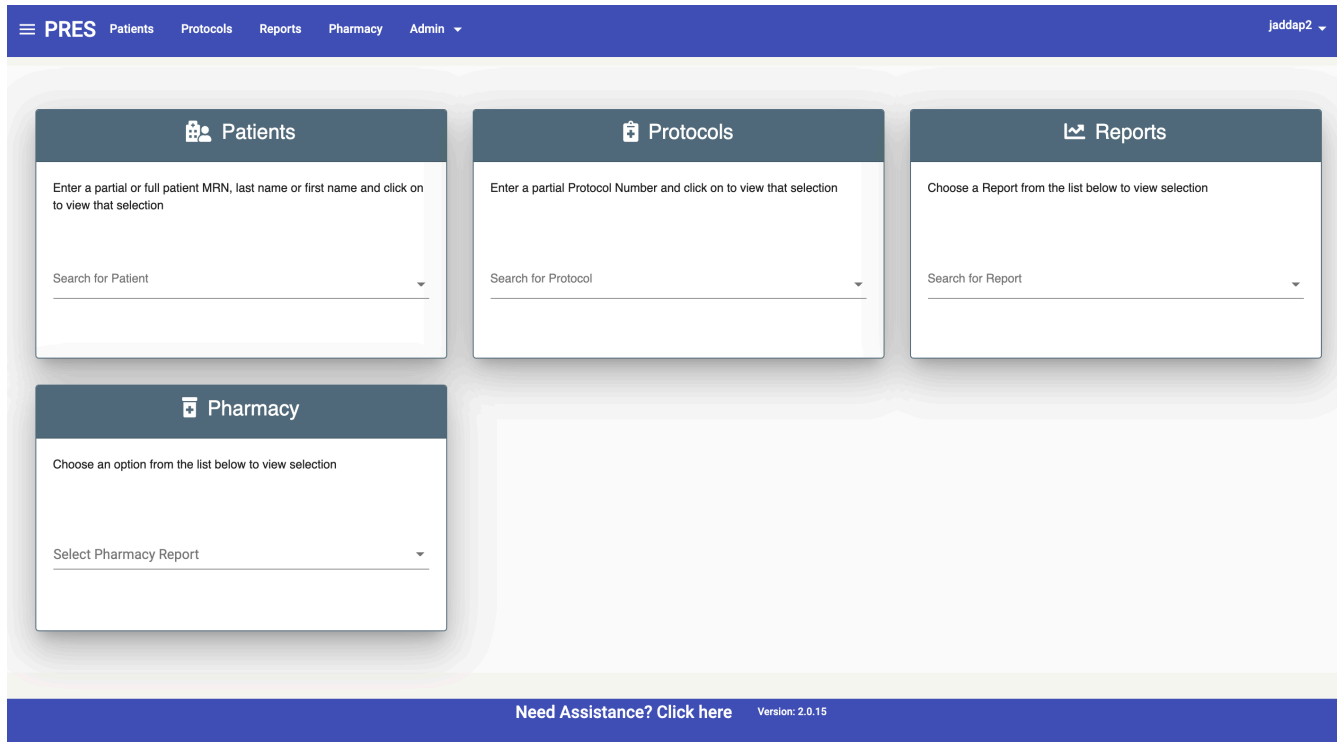


FIGURE 4 – ADMIN HOME PAGE

On every page of the application the user can go back to the home page by clicking the PRES link at the top of every page.



FIGURE 5 – MENU BANNER

The other links provide shortcuts to each page in the application.

Clicking the list icon in the title bar opens yet another navigation shortcut as seen below.

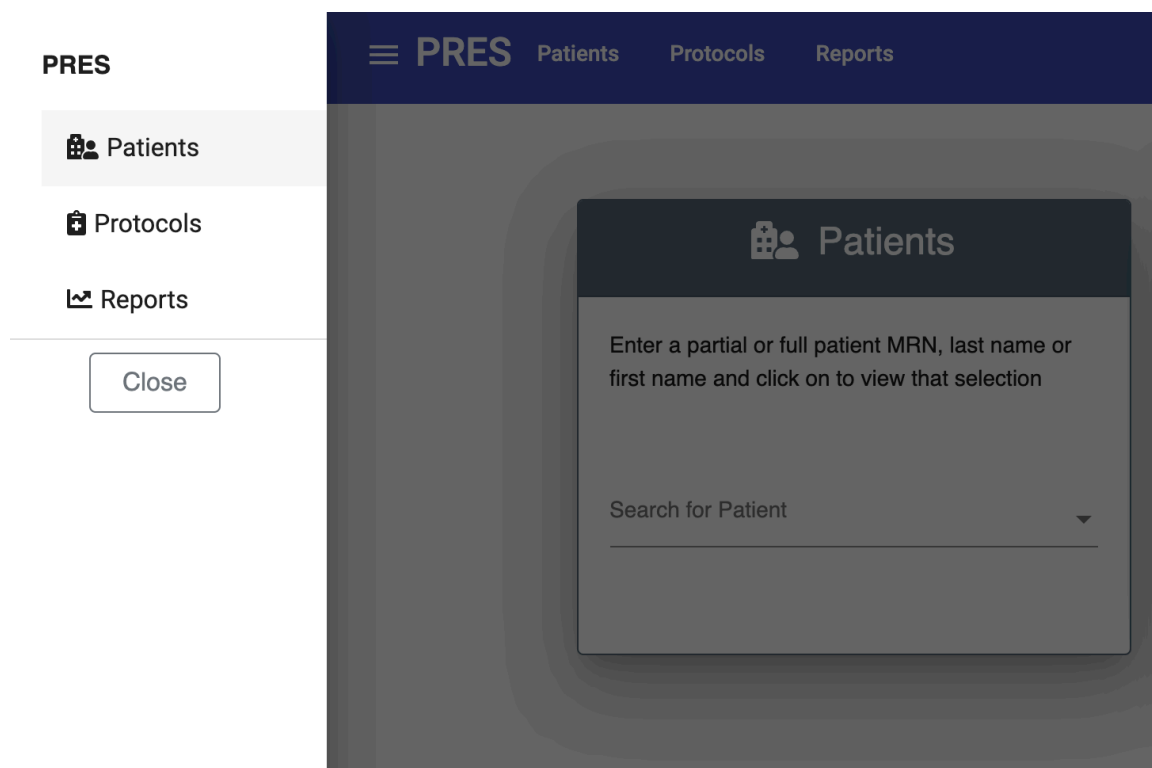


FIGURE 6 – SIDE MENU

The Patients tile on the home page allows the user to search for patients with partial (at least 2 characters) MRN or name.

The Protocols tile allows the user to search protocols by partial protocol number with or without dashes.

The Reports tile (for those with the privilege) allows the user to select and run standard reports.

The Pharmacy tile allows pharmacy users to quickly find new registrations.

There is no Register tile because the user must first select a patient or a protocol before the Register button is available.

SEARCHING AND SELECTING A PATIENT

You can find a patient in 3 different ways in PRES. First, on home page in Patients tile, Second on patient view page and Third on registration page.

To find a patient enter at least 2 characters which will open a drop-down list of patients already in PRES matching those characters:

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FIGURE 7 – MATCHING PATIENTS IN PRES

Select a patient by clicking on it or continue entering characters until the desired patient is found.

If a valid CRIS MRN is entered that is NOT found in PRES, the search result will indicate “CRIS” as the source of the patient as follows:

FIGURE 7 – CRIS PATIENT NOT IN PRES

Selecting a CRIS patient will import that patient into PRES.

If a valid CRIS MRN is entered and not found, please contact CRIS to verify the MRN.

If an outside patient is not found in PRES, the user is directed to select a multisite protocol first:

Patients

Enter a partial or full patient MRN, last name or first name and click on to view that selection

Search for Patient

new patient|

No Results Found. Create new patient via protocol enrollment process

FIGURE 8 - ADDING A PATIENT

Selecting a patient will open the [Patient View](#)

ADDING AN OUTSIDE PATIENT

Outside patients can ONLY be created while registering an outside patient to a multisite protocol after selecting an outside Institution:

Protocol Selection

Number: [20-C-0103](#)

Description: Investigation of the B- and T-cell repertoire and immune response in patients with acute and resolved COVID-19 infection

Category: Observational Study

Version: B

Is Screening: No

Is Two-step: No

Multi-Institutional: Yes

Randomized: No

Organization: Medstar Montgomery Medical Center

Patient Details

Patient Lookup: 838777483

838777483 [NOT FOUND - Create New]

FIGURE 9 - ADDING A PATIENT

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After clicking “(NOT FOUND – Create New)” in the Patient Lookup drop down the user will be able to enter the outside patients’ demographics:

Protocol Selection

Number: 6

Description: In

Category: C

Version: B

Is Screening: No

Is Two-step: No

Multi-Institutional: Yes

Randomized: No

Organization:

Patient Details

Patient Lookup:

Add New Patient

Organization *
Medstar Montgomery Medical Center

First Name *
John

Last Name *
Doe

MRN *
838777483

Date Of Birth *
1/31/1973

Gender *
Female

Race *
White

Ethnicity *
Not Hispanic or Latino

Close

Create Patient

FIGURE 10 – CREATE PATIENT

PATIENT VIEW

The Patient View page displays patient information such as demographics, the protocols in which the patient is participating, and the medical records for each institution that the patient is been treated by.

Patient participating protocols table shows patient enrollments from PRES and CDR applications. Enrollment with PRES value in source column present in PRES and CDR source enrollment retrieved from CDR. However only PRES protocols and enrollments can be viewed in detail

Patient:

Full Name:
Change Patient

Medical Records:
Add Medical Record

DOB: 10/23/1958

DOD: --

Gender: Male

Race: White

Ethnicity: Not Hispanic or Latino

Participating Protocols
Register New

PDF
Excel

Search for enrollments

| Source | Protocol | Protocol Status | Protocol Phase | PI | Registration Date | Last Event Date | Last Event Type | Sequence Number | Organization | Actions |
|--------|-----------|--|-------------------------|------------------|-------------------|-----------------|-----------------|-----------------|---|----------------------|
| PRES | 20-C-0076 | Open - Recruiting | Clinical Trial Phase II | Kreitman, Robert | 10/29/2020 | 10/29/2020 | Fully Eligible | 1010001 | National Institutes of Health Clinical Center | View |
| PRES | 01-C-0129 | Open - Recruiting | | Gulley, James | 09/22/2020 | 09/22/2020 | Fully Eligible | 17522 | National Institutes of Health Clinical Center | View |
| CDR | 96-C-0071 | Open - No Longer Recruiting - Follow-up Only | | Gulley, James | 06/08/2016 | 06/08/2016 | Fully Eligible | 980 | NCI | N/A |
| PRES | 10-C-0066 | Open - Recruiting | | Kreitman, Robert | 04/30/2015 | 04/30/2015 | Fully Eligible | 307 | National Institutes of Health Clinical Center | View |
| PRES | 01-C-0129 | Open - Recruiting | | Gulley, James | 04/30/2015 | 06/17/2015 | Off-Study | 10675 | National Institutes of Health Clinical Center | View |

Items per page: 10
1 - 5 of 5

FIGURE 11 - PERSON VIEW

From this view it is possible to modify an existing outside MRN, [retrieve protocol data](#), [register the patient to a new protocol](#), and view the [patient's enrollment status](#) for the selected protocol.

ADD MEDICAL RECORD

Clicking the “Add Medical Record” button of the details section of the person view allows the user to add an outside institution’s MRN to the selected patient. This section also allows to edit existing outside MRNs. CRIS

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MRNs can NOT be modified as they are validated against CRIS. PRES will ensure that MRNs are unique within an institution.



The screenshot shows a web form titled "Add MRN and Institution" with a close button (X) in the top right corner. The form contains a dropdown menu labeled "Select Organization" and a text input field labeled "MRN *". At the bottom right, there are two buttons: "Close" and "Save" (which is highlighted in blue and includes a save icon).

FIGURE 12 - ADD OR MODIFY MRN

PROTOCOL VIEW

The protocol view page displays the available information for the protocol. For a detail of the available information please see the figure below:

Protocol: 10-C-0025

Number: # 10-C-0025 [Change Protocol](#)
Branch: Laboratory of Molecular Biology
Status: Open - Recruiting
Randomized: Yes
PI: Robert, Kreitman
Masking: Open
Description: Randomized Phase II Trial of Rituximab with Either Pentostatin or Bendamustine for Multiply Relapsed or Refractory Hairy Cell Leukemia
Multi-Institutional: Yes [View - \(0 Sites\)](#)

Ceiling: 74 (-16 Open)
ProtocolCategory: Interventional or Clinical Trial
Is Screening: No
Collect Registering PI: No
Is two-step: No
Cohorts: Cohort 1 (Dose escalation): Up to 12 pts with HCL, HCLv or unmut.IGHV4-34+ HCL/HCLv enrolled to Arm 1/2 for tolerability; pts with relapse/no response may crossover to Arm 4 (closed)
Cohort 2 (Dose expansion; randomized): Up to 56 evaluable pts with HCL, HCLv or unmut.IGHV4-34+ HCL/HCLv to be randomized and stratified and enrolled to Arm 3/4; pts with relapse/no response may crossover to the other arm.
Cohort 3 (Dose expansion; non-randomized): Up to 4 evaluable pts with HCL, HCLv or unmut. IGHV4-34+ HCL/HCLv with prior non-response to either study therapy not to be randomized and to be enrolled to Arm 3 or 4
Arms: 4 [View](#)

Enrolled Patients [Register New](#)

PDF Excel

Search for data

| Full Name | MRN | Registration Date ↓ | Last Event Date | Last Event Type | Sequence Number | Organization | Actions |
|-----------|-----|---------------------|-----------------|-----------------|-----------------|--------------|--|
| L | 7 | 3 | 05/08/2020 | 05/08/2020 | Fully Eligible | 64 | National Institutes of Health Clinical Center View |
| E | 8 | 1 | 03/23/2020 | 05/08/2020 | Off-Treatment | 63 | National Institutes of Health Clinical Center View |
| C | 7 | 1 | 03/17/2020 | 03/17/2020 | Fully Eligible | 62 | National Institutes of Health Clinical Center View |
| C | 7 | 0 | 09/23/2019 | 09/23/2019 | Fully Eligible | 61 | National Institutes of Health Clinical Center View |
| A | 7 | 8 | 09/16/2019 | 09/16/2019 | Fully Eligible | 60 | National Institutes of Health Clinical Center View |
| L | 7 | 1 | 05/13/2019 | 05/13/2019 | Fully Eligible | 59 | National Institutes of Health Clinical Center View |
| C | 3 | 1 | 04/03/2019 | 04/03/2019 | Fully Eligible | 58 | National Institutes of Health Clinical Center View |
| J | 7 | 7 | 03/22/2019 | 02/10/2020 | Off-Treatment | 57 | National Institutes of Health Clinical Center View |
| C | 7 | 8 | 03/20/2019 | 03/20/2019 | Fully Eligible | 56 | National Institutes of Health Clinical Center View |
| C | 7 | 1 | 03/07/2018 | 10/08/2019 | Off-Study | 55 | National Institutes of Health Clinical Center View |

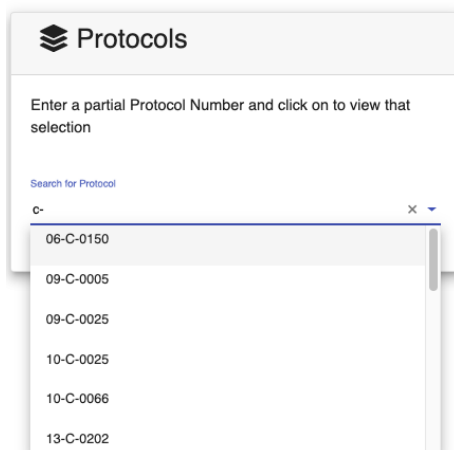
Items per page: 10 1 - 10 of 90 |< < > >|

FIGURE 17 - PROTOCOL VIEW

SEARCHING AND SELECTING A PROTOCOL

To find a protocol click on the “Search for a Protocol” field and enter at least 2 characters which will open a drop-down list of protocols already in PRES matching those characters:

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The screenshot shows a web interface titled "Protocols". Below the title, there is a text prompt: "Enter a partial Protocol Number and click on to view that selection". Underneath this is a search bar with the placeholder text "Search for Protocol". The search bar contains the text "C-" and has a dropdown menu open. The dropdown menu lists the following protocol numbers: "06-C-0150", "09-C-0005", "09-C-0025", "10-C-0025", "10-C-0066", and "13-C-0202". The first item, "06-C-0150", is highlighted. The search bar has a clear button (X) and a dropdown arrow.

| Protocol Number |
|-----------------|
| 06-C-0150 |
| 09-C-0005 |
| 09-C-0025 |
| 10-C-0025 |
| 10-C-0066 |
| 13-C-0202 |

FIGURE 16 - PROTOCOL SEARCH

Clicking on a protocol will open the [Protocol View](#) page.

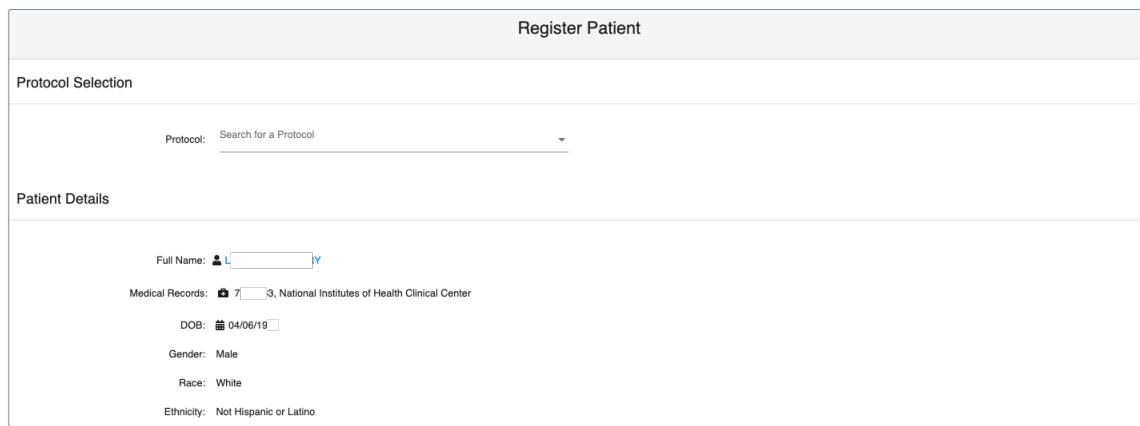
CREATING A REGISTRATION

A registration can be created from the Patient View or the Protocol View as illustrated below by clicking the “Register New” button to the right of the “Participating Protocols” or the “Enrolled Patients” header.

In both cases, after selecting the “Register New” button, the user will be redirected to the [Register Patient](#) page.

REGISTER PROTOCOL FROM PATIENT PAGE

Since the patient is already selected the protocol must be selected by clicking on the “Search for a Protocol” field and entering at least 2 characters which will open a drop-down list of protocols already in PRES matching those characters:



The screenshot shows the 'Register Patient' form. It has a header 'Register Patient'. Below it is a section 'Protocol Selection' with a search bar labeled 'Protocol: Search for a Protocol'. Below that is a section 'Patient Details' with the following fields: 'Full Name: [text input]', 'Medical Records: [checkbox] 7 [text input] 3, National Institutes of Health Clinical Center', 'DOB: [calendar icon] 04/06/19 [text input]', 'Gender: Male', 'Race: White', and 'Ethnicity: Not Hispanic or Latino'.

FIGURE 18 - REGISTER PROTOCOL TO PATIENT PAGE

The protocol will be selected by clicking the desired protocol from the results drop down. After selecting the protocol, a summary of the protocol’s information will be displayed. This information also notifies the user if it is open to enrollment or not.

In the figure below the selected protocol is not open for enrollment. The error banner in red explains the reason. In this case there are no cohorts available in the protocol.

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The screenshot shows the 'Register Patient' form. At the top is a header bar labeled 'Register Patient'. Below it is a section titled 'Protocol Selection'. Inside this section, there is a dropdown menu for 'Protocol' with the value '13-C-0202'. Below the dropdown is a detailed view of the selected protocol, including its number, description, version, and various attributes like 'Is Screening', 'Is Two-step', 'Multi-Institutional', and 'Randomized'. The 'Organization' is listed as 'National Institutes of Health Clinical Center'. At the bottom of the form is a section titled 'Patient Details'.

Register Patient

Protocol Selection

Protocol: 13-C-0202

Number: 13-C-0202

Description: Tissue Procurement and Natural History Study of Patients with Malignant Mesothelioma and Other Mesothelin Expressing Cancers

Version: J

Is Screening: No

Is Two-step: No

Multi-Institutional: No

Randomized: No

Organization: National Institutes of Health Clinical Center

Patient Details

FIGURE 19 – REGISTER PROTOCOL TO PATIENT

REGISTER PATIENT FROM PROTOCOL PAGE

PRES also allows a patient to be added to a protocol from the protocol page

The screenshot shows the 'Register Patient' form. At the top is a header bar labeled 'Register Patient'. Below it is a section titled 'Protocol Selection'. Inside this section, there is a dropdown menu for 'Number' with the value '10-C-0025'. Below the dropdown is a detailed view of the selected protocol, including its description, version, and various attributes like 'Is Screening', 'Is Two-step', 'Multi-Institutional', and 'Randomized'. The 'Organization' is listed as 'National Institutes of Health Clinical Center'. At the bottom of the form is a section titled 'Patient Details'. Below this section is a dropdown menu for 'Patient Lookup' with the value 'Search for Patient'.

Register Patient

Protocol Selection

Number: 10-C-0025

Description: Randomized Phase II Trial of Rituximab with Either Pentostatin or Bendamustine for Multiply Relapsed or Refractory Hairy Cell Leukemia

Version: W

Is Screening: No

Is Two-step: No

Multi-Institutional: Yes

Randomized: Yes

Organization: National Institutes of Health Clinical Center

Patient Details

Patient Lookup: Search for Patient

FIGURE 20 - REGISTER PATIENT TO PROTOCOL PAGE

Since the protocol is already selected the user must use the “Search for a Patient” field to select a patient.

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Once the Patient and Protocol are selected the user can proceed to provide additional details on the Register Patient page which is dynamic and displays additional fields as data is entered. The Register button will remain inactive until all fields have been populated.

Miscellaneous

Disease: Acute Leukemia ✕ ▼

Registering Branch: Laboratory of Molecular Biology ✕ ▼

Registering PI: Alewine, Christine ✕ ▼

Screened for Protocols: ✕ 16-C-0128 ✕ 19-C-0128 ✕ ▼

FIGURE 21 - REGISTER PATIENT TO PROTOCOL PAGE

In miscellaneous section Disease input required and Registering Branch, Registering PI and Screened for Protocols inputs are only shown and required for screening protocols i.e. 01C0129

Once the Eligible for Treatment box is checked the Cohort selection field will be displayed.

Eligibility Status

☒ Eligible for Treatment
☐ Not Eligible

Fully Eligible Date: 7/1/2020 📅

Assignment Details

[Search for a Cohort](#)

Cohort: ▼

FIGURE 22 - REGISTER PATIENT TO PROTOCOL PAGE

After selecting a Cohort, the Arm selection field is displayed showing only the selected cohort's arms.

Eligibility Status

☒ Eligible for Treatment
☐ Not Eligible

Fully Eligible Date: 7/1/2020 📅

Assignment Details

Cohort: Cohort 1 (Dose escalation): Up to 12 pts with HCL, HCLv or unmut. IGHV4-34+ HCL/HCLv enrolled to Arm 1/2 for tolerability; pts with relapse/no response may crossover to Arm 4 (closed) ✕ ▼

[Search for a Cohort Arm](#)

Cohort Arm(s): ▼

Arm 1: Rituximab +bendamustine at 70 mg/m2 for initial tolerability study (closed)

Arm 2: Rituximab +bendamustine at 90 mg/m2 for initial tolerability study (closed)

FIGURE 23 –
SELECT ARM

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Once all fields have been populated the Register button will be activated. The registration will be recorded after clicking the Register button. After successful registration the user will be taken to the Enrollment View.

RANDOMIZATION


For randomized cohorts the arm will be assigned as per the randomization sheets and blinded as necessary. Protocols are randomized in one of the 2 ways, Stratified and Non-Stratified. For Stratified protocols, Cohort, Stratification Factor question and answer must be selected. For Non-Stratified protocols just Cohort selection is required.

Eligibility Status

☒ Eligible for Treatment
☐ Not Eligible

Fully Eligible Date: 11/9/2020 

Assignment Details


Cohort: 1: Patients with HCL with (62 patients) and without (68 subjects) prior course of purine analog to be randomized between Arm 1 and Arm 2 (randomization stratified based upon prior purine analog... 

Select Stratification Level

Prior CdA:

1 + Prior CdA

No Prior CdA



TWO STEP AND THREE STEP PROTOCOLS

For two step and three step protocols the Eligibility Status includes the “Eligible for Screening” option.

Eligibility Status

☐ Eligible for Screening
☐ Eligible for Treatment
☐ Not Eligible

FIGURE 24 – TWO STEP

After screening the Eligibility Status can be updated to Eligible for Treatment or Not Eligible.

ENROLLMENT VIEW

The enrollment view shows the patient's status of the enrollment for the selected protocol. This section can only be accessed re by clicking the view icon in the participating protocols (Patient view) or enrolled patients (protocol view).

Enrollment View: TEMMER, ROBERT on 10-C-0025 W

Patient Details

Full Name: T T [Edit](#)

Medical Records: 4 37, National Institutes of Health Clinical Center

DOB: 09/03/19

DOD: --

Protocol Details

Number: 10-C-0025 W [Edit](#)

Name: 10-C-0025

PI: Kreitman, Robert

Interventional Model: Crossover

Assignment Details

Sequence Number: 20 [Edit](#)

Cohort Details: Cohort 2 (Dose expansion; randomized)(Up to 56 evaluable pts with HCL, HCLv or unmut.IGHV4-34+ HCL/HCLv to be randomized and stratified and enrolled to Arm 3/4; pts with relapse/no response may crossover to the other arm.)

Stratification Group: Purine: Purine Sensitive

Allocated Slot: 53

Arm Details: Arm 3 Rituximab + Bendamustine (at the tolerated dose)

Disease Code: Hairy Cell Leukemia [Edit](#)

Events of Significance

Type of Date:

Date: 7/1/2020

Comments:

[Add Event](#)

| Date | Date Type | Comments | Actions |
|------------|----------------|---------------|----------------------|
| 08/10/2011 | Consent | #53_Sensitive | Edit |
| 08/10/2011 | Registration | #53_Sensitive | |
| 08/10/2011 | Fully Eligible | #53_Sensitive | Edit |

FIGURE 13 - ENROLLMENT VIEW

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By clicking in the patient name the user will be redirected to the [Patient View](#), clicking in the protocol number will show the [Protocol View](#).

It is also possible to add/edit the Sequence Number, add/modify the dates of the events of significance, for the patient in the selected protocol.

While editing the Sequence Number the next available sequence number is displayed along with a link to Use This Number.

Edit Sequence Number

Sequence Number:

Next Available Sequence Number: 65 [Use This Number](#)

Show used sequence numbers for 10-C-0025

[Close](#) [Save Changes](#)

FIGURE 14 – SEQUENCE NUMBER

In addition, there is an option to view the existing Sequence Numbers in this Protocol.

Edit Sequence Number

Sequence Number:

Next Available Sequence Number: 19 [Use This Number](#)

Hide used sequence numbers for 09-C-0025

Search for sequence numbers

| Patient | Consent Date ↓ | Sequence Number |
|---------|----------------|-----------------|
| S | 12/22/2015 | 18 |
| C | 03/12/2014 | 17 |
| T | 01/29/2014 | 16 |
| C | 04/18/2013 | 15 |

[Close](#) [Save Changes](#)

FIGURE 15 – USER SEQUENCE NUMBERS

TWO STEP PROTOCOLS

Patients registered with Eligible for Screening option during initial registration for 2 step and 3 step protocols are eligible receive treatment. Patient Cohort/Arm can be selected on enrollment view. For randomized protocols Cohort (and stratification information for stratified protocols) needs to be selected.

Eligibility Status

☒ Eligible for Treatment
☐ Not Eligible

Fully Eligible Date: Enter Fully Eligible Date
 11/9/2020

Assignment Details

Cohort: Select Cohort
 Cohort 3 (Dose expansion; non-randomized): Up to 4 evaluable pts with HCL, HCLv or unmut. IGHV4-34+ HCL/HCLv with prior non-respons... × ▾

Cohort Arm(s):
 Arm 3: Rituximab + Bendamustine (at the tolerated dose)
 Arm 4: Rituximab + Pentostatin

Checking Not Eligible will prompt the user to confirm that the patient should be taken off study. These patients counted as screen failure

Eligibility Status

☐ Eligible for Treatment
☒ Not Eligible

Take Off-Study

FIGURE 25 – NOT ELIGIBLE

THREE STEP PROTOCOLS

Three step protocols follow the same process as two step protocols and in addition they have 3rd step, in which patient assigned to different Cohort and Arm.

Cohort/Arm Change

Cohort: 2/Patients with Glioblastoma without sufficient vaccine created: GBM pts w/MRI findings consistent w/a suspected GBM or a histologically co... × ▾

Cohort Arm(s): 1/RT+TMZ + Pembrolizumab: Standard treatment with experimental treatment (pembro) added × ▾

Update

For example, 17-C-0034 is three step protocol with three steps

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1. Screening
2. Radiation Therapy
3. Receive Treatment

Patients are initially screened to the protocol, then receive radiation therapy and receive actual treatment in 3rd step

RANDOMIZATION

For randomized cohorts the arm will be assigned as per the randomization sheets and blinded as necessary. Protocols are randomized in one of the 2 ways, Stratified and Non-Stratified. For Stratified protocols, Cohort, Stratification Factor question and answer must be selected. For Non-Stratified protocols just Cohort selection is required.

In masking(blinding) protocols, if the enrollment blind is broken, users with appropriate privilege can Skip the assigned slot for the next available after providing a justifying comment.

The screenshot shows the 'Assignment Details' form. At the top, it says 'Sequence Number: 64' with an 'Edit' link. Below that, 'Cohort Details: Cohort 2 (Dose expansion; randomized)(Up to 56 evaluable pts with HCL, HCLv or unmut.IGHV4-34+ HCL/HCLv to be randomized and stratified and enrolled to Arm 3/4; pts with relapse/no response may crossover to the other arm.)'. Then 'Stratification Group: Purine: Purine Sensitive'. The 'Allocated Slot: 76' is highlighted with a red box, and next to it is a red button labeled 'Skip Slot'. Below this is a 'Comments *' text area. At the bottom are 'Save' and 'Cancel' buttons. At the very bottom, it says 'Arm Details: Arm 4 Rituximab + Pentostatin'.

FIGURE 26 - SKIP

EVENTS OF SIGNIFICANCE

The Enrollment View shows the assignment details for a particular patient on a particular protocol.

CROSSOVER PROTOCOLS

Certain protocols allow patients to crossover from one arm to another in the same cohort. For such protocols the Crossover Event of Significance is available until the patient is take Off Treatment.

The screenshot shows the 'Events of Significance' form. It has a 'Type of Date' dropdown menu with 'Crossover' selected. Below it is a 'Date' field. Then there is a 'Comments:' label followed by a text area with the placeholder 'Enter your comments here'. At the bottom is a blue button labeled 'Add Event'.

FIGURE 27 - CROSSOVER

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TREATMENT PROTOCOLS

All registrations on treatment protocols have the following Events of Significance

Events of Significance

Type of Date: Off-Study
Off-Treatment

Date:

Comments:

[Add Event](#)

FIGURE 28 – OFF EVENTS

The Enrollment View displays the history of Events off Significance and allows users to edit the comments.

| Date | Date Type | Comments | Actions |
|------------|----------------|--------------------------|----------------------|
| 03/07/2018 | Consent | Refractory_NonRandomized | Edit |
| 03/07/2018 | Registration | Refractory_NonRandomized | |
| 03/07/2018 | Fully Eligible | Refractory_NonRandomized | Edit |
| 10/08/2019 | Off-Study | Refractory_NonRandomized | Edit |

FIGURE 29 – HISTORY OF EVENTS

REPORTS

This option allows the user to run a series of pre-determined reports within PRES.

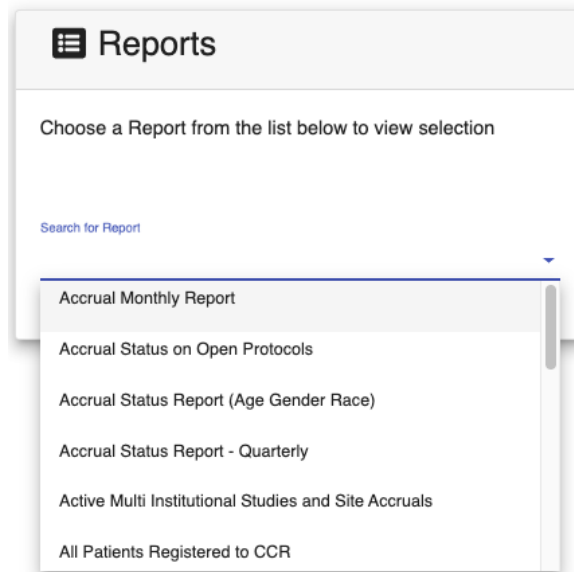


FIGURE 30 - REPORTS

Many of the reports accept parameters including Branch and Protocol.

A screenshot of the 'Disease Accrual Report' form in the PRES application. The form is titled 'Disease Accrual Report' and has a subtitle 'Select branch(s) and/or protocol(s). Leave blank to show all records'. There are two search fields: 'Search Branch:' with a dropdown menu showing 'Select Branch' and 'Search Protocol:' with a dropdown menu showing 'Select Protocol'. Below these fields is a blue button labeled 'Generate Report'.

FIGURE 31 – REPORT PARAMETERS

On some reports these parameters are optional, and the report can be generated for all protocols. Some reports have date parameters.

PRES User Guide

The screenshot shows the top navigation bar of the PRES application with the 'PRES' logo and links for 'Patients', 'Protocols', and 'Reports'. Below the navigation bar, the title 'Randomized Protocol Accrual Ceiling Report' is centered. The form contains two input fields: 'End Date' with the value '7/1/2020' and a calendar icon, and 'Protocol' with a dropdown menu showing 'Select Protocol'. A blue button labeled 'Generate Report' is positioned below the inputs. A small text note below the 'End Date' field reads: 'Please pick end date to filter the report. Defaults to today'.

FIGURE 32 – REPORT DATE

One PRES report currently allows the user to Include CDR Data. This is the Accrual Monthly Report as it needs to include all accruals whether in PRES or CDR.

The screenshot shows the top navigation bar of the PRES application with the 'PRES' logo and links for 'Patients', 'Protocols', and 'Reports'. Below the navigation bar, the title 'Accrual Monthly Report' is centered. The form contains three input fields: 'End Date' with the value '7/1/2020' and a calendar icon, 'Branch' with a dropdown menu showing 'Select Branch', and 'Include CDR Data' with an unchecked checkbox. A blue button labeled 'Generate Report' is positioned below the inputs. A small text note below the 'End Date' field reads: 'Please pick end date to filter the report. Defaults to today'.

FIGURE 32 – CDR DATA

When selecting to include CDR data there is another checkbox to indicate whether the CDR data to include should be Limited to Active Treatment protocols.

Following is the result page for the Randomized Protocol Accrual Ceiling report:

PRES User Guide

Randomized Protocol Accrual Ceiling Report

End Date: 7/1/2020 
Please pick end date to filter the report. Defaults to today

Protocol: Select Protocol ▼

Generate Report

Print

NCI

CONFIDENTIAL

CCR

Randomized Protocol Accrual Ceiling Report

Reporting Period Ending: 07/01/2020

Report generated on: 07/01/2020 15:46 PM

| Protocol | PI | Ceiling | Arm Name | Arm Description | 1st On-Study Date | Q3 2019 | Q4 2019 | Q1 2020 | Q2 2020 | Cumulative Accrual |
|-----------|------------------|---------|----------|---|-------------------|---------|---------|---------|---------|--------------------|
| 10-C-0025 | Robert, Kreitman | 74 | | | | | | | | |
| | | | Arm 1 | Rituximab +bendamustine at 70 mg/m2 for initial tolerability study (closed) | 06/23/2010 | 0 | 0 | 0 | 0 | 6 |
| | | | Arm 2 | Rituximab +bendamustine at 90 mg/m2 for initial tolerability study (closed) | 11/10/2010 | 0 | 0 | 0 | 0 | 6 |
| | | | Arm 3 | Rituximab + Bendamustine (at the tolerated dose) | 06/22/2011 | 1 | 0 | 2 | 0 | 28 |
| | | | Arm 4 | Rituximab + Pentostatin | 06/24/2010 | 1 | 0 | 0 | 1 | 24 |
| 09-C-0005 | Robert, Kreitman | 177 | | | | 2 | 0 | 2 | 1 | 64 |
| | | | 1 | Cladribine with immediate Rituximab | 04/06/2009 | 1 | 0 | 0 | 0 | 62 |
| | | | 2 | Cladribine with Rituximab delayed by at least 6 months after Cladribine if and when minimal residual disease is detected | 04/02/2009 | 0 | 0 | 0 | 0 | 59 |
| | | | 3 | Non-randomized group receiving Cladribine with immediate Rituximab (before rather than after the 1st of the 5 daily doses of cladribine on day 1) | 04/22/2009 | 0 | 0 | 0 | 0 | 44 |
| | | | | | | 1 | 0 | 0 | 0 | 165 |

FIGURE 33 - RANDOMIZED ONLY WITH ARMS REPORT

ISSUES AND FEEDBACK

Clicking the “Need Assistance?” link at the bottom of every page opens a dialog box that allows the user to report issues or suggestions regarding the use of the application.

Please provide your feedback below. Any details that led up to an error will help us investigate the issue.

Summary*

Name*

Email Address*

Description

Attach file No file chosen

We've currently got you logged in as Christo Andonyadis. This feedback will be created using this user unless this is not you.

☐ Include data about your current environment, like the browser and page URL. This helps us understand your feedback better.

[What is included in the data about my current environment?](#)

FIGURE 34 - ISSUES AND FEEDBACK

We recommend checking the “Include data about your current environment” box if the assistance is needed for a particular protocol or patient or report. The Office of Information Technology (OIT) will receive the feedback, the user will be identified as the reporter of the issue and receive an email confirming that the ticket has been received.

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